

Global Collaboration on Biotechnology Risk Assessment

Mark Segal

Senior Microbiologist

U.S. EPA Office of Prevention Pesticides and Toxic Substances (OPPTS)/Office of Pollution Prevention and Toxics (OPPT)

(202) 564-7644

segal.mark@epa.gov

Authors: Mark Segal

U.S. EPA OPPTS/OPPT

Keywords: biotechnology, risk assessment, global collaboration, microbe, identification

A reliable species identification is essential for governmental risk assessment of bacteria used in biotechnology. The U.S. Environmental Protection Agency (U.S. EPA) experience with biotechnology reviews for submissions using pseudomonad bacteria has shown that consistent identification of these species is difficult. Canadian government experience has been similar. Many, including the regulated community, share government's need to know which identification methods produce the most reliable results for given species. The U.S. EPA has sponsored collaborative research with the goal of assisting both submitters to the U.S. EPA as well as government assessors to determine the best approaches to identifying pseudomonads. Canadian government agencies have been part of that collaboration for more than a decade. The U.S. EPA led the initial stages in the 1990s, and Health Canada (HC) leads the current projects.

The most recent joint effort is a laboratory comparison of identification methods involving eight analytical laboratories from seven countries on three continents, plus a coordination center in Canada. Several of these are government laboratories that are part of the environmental or public health infrastructure of their respective nations. While the U.S. EPA and HC are focusing on the use of the study to assist the user community in biotechnology product evaluation, others may use the results to address public health or environmental problems associated with these same bacteria. Thus, this project is a truly global collaborative effort addressing multiple environmental needs.

Project officers from both the U.S. EPA and HC have used their collective experiences coming from these projects to collaborate with the Organisation for Economic Co-operation and Development (OECD) colleagues to produce guidance documents published through the OECD on issues of microbial identification and biotechnology risk assessment. Data from the various projects have been presented at prominent scientific meetings and are being prepared for peer-reviewed publication.